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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/661,588	SCHREDER ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed September 23, 2010 is acknowledged. New claims 17 and 18 are presented. Accordingly, claims 1, 3-5 and 9-18 are now under consideration.

A Terminal Disclaimer filed September 23, 2010 is further acknowledged and has been approved.

Applicants' arguments have been fully considered. Rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The following rejection constitutes the only rejection presently applied to the instant claims.

Claims 1, 3-5 and 9-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Mitra et al., 5,955,105, and further in view of Remington's Pharmaceutical Sciences, in the last Office Action. It was asserted Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent is present. Reynolds teaches a concentration range of l-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. A micronized form of levothyroxine with a particle size between 5 and 25 μm is conventional. Mitra teaches stability problems are associated with pharmaceutical preparations comprising thyroxine. Pharmaceutical preparations containing levothyroxine hormone exhibit a relatively short shelf life, and conditions of high humidity and temperature result in stability issues. Mitra makes the point that proper selection of a binder, as well as a filler, a disintegrant, a glident and a lubricant,

produces a stable formulation for levothyroxine or other thyroid preparations in solid dosage form. Remington, which for over 100 years, has been the definitive textbook and reference on the science and practice of pharmacy, teaches materials commonly used as binders include starch, gelatin and sugars, such as sucrose, glucose, dextrose, molasses and lactose. These binders impart a cohesiveness to the tablet formulation which insures that the tablet remains intact after compression.

Applicants argue the disclosed materials of Reynolds are not free of organic solvent and Mitra does not teach the avoidance of lactose, glucose, sucrose, etc. as binders with thyroxine. Mitra refers to them as fillers. Applicants make the point that gelatin functions as a binder in the instant formulation. Gelatin is dissolved and used as a solution, and levothyroxine is suspended therein. Applicants further argue the two declarations filed February 11, 2008 indicate better stability with gelatin in thyroid hormone formulations. In the first Declaration, comparison is made between a formulation containing gelatin, and one containing the polymer HPMC, (hydroxypropylmethylcellulose). Where gelatin is substituted for HPMC as a binder, active agent content over time is significantly greater for compositions formulated with gelatin then the active agent content maintained for those formulated with HPMC. In the second Declaration a formulation containing a small amount (2.50 mg) of gelatin as binder has a better stability than the same formulation containing 3.50 mg HPMC, which is the most frequently used binder.

Applicants' arguments have been given careful consideration and are persuasive in part. The declarations indicate better stability of the formulation containing a small

amount (2.50 mg) of gelatin as binder than the same formulation containing 3.50 mg HPMC. Accordingly, a claim drawn to Formulation A would be given favorable consideration. However, as previously indicated, Applicants have not demonstrated unexpected results commensurate in scope with the claims.

According to Remington, the quantity of binder used has considerable influence on the characteristics of the final compressed tablet. Further, there is no organic solvent utilized in the tablet formulations disclosed in column 6.

The rejection of record under 35 U.S.C. 103 is maintained and presently extended to include new claims 17 and 18.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 2, 2010

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614